UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545
This Document Relates to All Cases	Master Docket Case No. 1:14-cv-01748 Hon. Judge Matthew F. Kennelly

JOINT STATUS REPORT REGARDING DEPOSITIONS AND PRODUCTION OF CUSTODIAL FILES

At the August 14, 2015 Case Management Conference, the Court directed the parties to confer and submit a report on the following three issues related to custodial files: (a) the PSC's identification of the next wave of witnesses to be deposed so that the MDL can continue to move forward and those custodial files can be produced prior to the deposition; (b) the production of custodial files "un-tethered" to a deposition; and (c) a presumptive limit or cap on the number of custodial files the PSC receives. The parties held phone calls on August 19 and August 23, 2015 where these issues were discussed. Unfortunately, the parties were unable to reach agreements on the timing of the custodial file production and the presumptive limit on the number of custodial files the PSC will be permitted to request.

I. Prioritization of Deponent Files

Agreed: The parties have agreed that on or before September 10, 2015, the PSC shall provide AbbVie with the next group of three (3) to (5) witnesses to be deposed so that their custodial files can be prioritized.

Plaintiffs' Position: Moving forward, the PSC will use its best efforts to identify the next group of witnesses for deposition in a timely manner in order to allow defense adequate time to produce the respective custodial files.

AbbVie's Position: AbbVie recognizes Plaintiffs' desire to have some additional information from the upcoming document productions and depositions before selecting additional deponents beyond those agreed to above. AbbVie has requested that the next 5 deposition witnesses (presumably for deposition in January) be identified by the end of November. This will assure that the deposition track continues without a hiatus, while, as indicated below, at the same time providing Plaintiffs with additional files not tied to depositions.

II. Custodial File Cap

Plaintiffs' Position: At the last Case Management Conference, AbbVie's counsel reiterated their request that the Court impose a presumptive limit on the number of custodians Plaintiffs would be entitled to in generic discovery. In particular, AbbVie proposed that Plaintiffs be presumptively limited to sixty-five (65) custodians, subject to the PSC having the ability to seek an additional ten (10) custodians on a showing of good cause. AbbVie's proposal applies to non-sales force employees sought through the PSC's generic discovery efforts (in contrast to the sales representatives who "called on" individual or bellwether plaintiffs' doctors and the district or regional managers of those sales representatives). Based on the Court's comments at the most recent conference, the PSC understands that the Court intends to impose a presumptive cap on the number of AbbVie custodial files the PSC will receive (from corporate custodians in the generic case as opposed to case-specific sales force and district/regional personnel), subject to some kind of "escape valve" to seek more files at some point in this MDL.

First, in light of the fact that at the current time the PSC is proposing to receive the Tier A and B files only (for a total of approximately 58 files), the PSC respectfully submits that any reasonable presumptive limit is not threatened by the current status and that once the PSC has received these files we will be in a better position to select a presumptive limit that is not arbitrary, but instead based on an analysis of the information produced. At the last case management conference, AbbVie argued that the cap should be "proportional" to the number of depositions. The concept of "proportionality," however, relates to the burden as compared to the total amount at issue in the litigation. Here, that is a very large amount given the dynamics of this case and this MDL. Regardless, the bottom line is that even AbbVie's proposed cap of sixty-five (65) plus ten (10) is not threatened by the current status if AbbVie produces the Tier A and B files.

Make no mistake, the PSC understands that it will not be receiving an unlimited universe of files for the reasons that the Court has made clear. The PSC, however, seeks a little more time and more of the requested files before being required to agree to a number for that limit. If the PSC was required to agree to a number at this time, the number would merely be a multiplier of the number of depositions and not something rationally based on the number of corporate employees who had a role in these products spanning several decades.

Second, Plaintiffs believe that AbbVie's cap proposal will substantially limit Plaintiffs' preparation of their generic case concerning AndroGel. The Court has permitted the PSC to take forty-three (43) generic discovery depositions from AbbVie. As the Court and AbbVie have acknowledged, the PSC should not be limited to only receiving custodial files for witnesses it elects to depose. Indeed, beyond the initial wave of depositions that the PSC has noticed, the PSC will be selecting future deponents based on the content of the custodial files that AbbVie

produces. In short, the content of the AbbVie witness custodial files will be driving the selection of witnesses that the PSC wishes to depose. Plaintiffs anticipate that AbbVie will make similar elections following its broad collection of records from plaintiffs' medical providers to make their elections as to who they wish to depose.

The issue, as AbbVie has framed it, is identifying the appropriate custodial file multiplier to which the PSC is entitled. Setting aside AbbVie's "good cause" supplement, AbbVie proposes a presumptive 1.5 custodial file multiplier for every deponent to which the PSC is permitted (1.5 x 43 = 65 [64.5]). In the context of this case, which includes AndroGel's development and marketing period as well as the involvement and transition of multiple corporations who fulfilled those functions, the PSC believes that AbbVie's proposal is simply unrealistic and that a formula based on the number of depositions should not be employed. Rather, the Court and the parties should look at the facts of the case and these products — which have been in development and on the market for close to two decades with a long regulatory history and countless numbers of employees who have had a significant role with these products — in determining what is reasonable. Tellingly, AbbVie has not once advised the Court or the PSC the total number of employees who had a role with these drugs (even limited to those with a significant role) since the time AndroGel was first developed. As demonstrated by the Rule 30(b)(6) deposition, that number far exceeds the individuals identified in AbbVie's Initial Disclosures.

The timeline for AndroGel spans nearly twenty years. Based on the PSC's review of custodial files and corporate organizational 30(b)(6) deposition, there are hundreds of Abbott/AbbVie employees that have played seemingly important roles and functions in various departments for these drugs over the years, including but not limited to: clinical development,

non-clinical development, regulatory, pharmacovigilance/drug safety, marketing, sales, medical affairs, and product management. Complicating this reality is the fact that these drugs were initially developed and brought to market — and marketed for 10 years — by Besins in partnership with Solvay prior to the product being sold to Abbott (along with the subsidiary who had responsibility for the product — Unimed) and then being spun-off to AbbVie. The PSC is still trying to learn exactly what information AbbVie has related to regulatory affairs, medical affairs and pharmacovigilance from the Solvay time period.[1]

AbbVie's proposed cap simply does not reasonably account for this broad development period and involvement of employees across multiple corporate affiliates during that time. AbbVie's proposal will leave a substantial number of custodians, their files, and windows of time inappropriately obscured from discovery, and will fail to ensure appropriate context for the selection and examination of witnesses, nor appropriately develop generic discovery for the more than 1,325 AbbVie cases currently on file already in the MDL.

Though AbbVie has indicated a desire to negotiate and fix a custodial file cap now based on the present state of Plaintiffs' knowledge of potential custodians and the Court's inclination to impose one, Plaintiffs have asked AbbVie to defer negotiations on that cap pending Plaintiffs' efforts to more specifically identify the custodians for whom AbbVie actually has files and until such a time when a reasonable cap would be implicated by the requested files. From AbbVie's statements at the July 20 Case Management Conference, Plaintiffs now understand that there may be a significant number of former Unimed/Solvay custodial files for whom AbbVie does not have custodial files. The PSC is attempting to discern the scope of custodial file gaps and

[1] The PSC received material about the marketing of AndroGel from the *King v. Solvay* production and is not seeking to re-visit that issue or production, but based on the allegations in the *King* case, that case was about the manner in which AndroGel was marketed.

potential implications to the identification of surrounding custodians to capture relevant discovery that was not transitioned from Solvay to Abbott/AbbVie.

The PSC proposes that Plaintiffs be given time to confer with Solvay's and AbbVie's counsel to more accurately identify and characterize the scope of this issue over the next thirty (30) to sixty (60) days (a time frame during which AbbVie will not have even produced all of the Tier A and B custodial files) to see if an agreement on a custodial file cap can be reached thereafter. As noted above, based on the prioritization method proposed, the PSC's outstanding custodial requests are well within any reasonable cap that may be imposed or agreed to and are still within the cap that AbbVie has proposed.

AbbVie's Position: AbbVie's position on custodial file production, both as to cap and as to schedule, is consistent with the fundamental goal of conducting the discovery process in a fair, balanced and efficient manner, which assists the parties to develop the facts needed to press and defend the cases. The Court should not allow one side to wield discovery as a weapon for achieving unfairness, but this is precisely what will happen under Plaintiffs' proposal. The unfairness is only exacerbated by the massive quantity of electronic documents still to be produced in the coming months. Plaintiffs have a massive tactical advantage when it comes to e-discovery; they can do targeted, automated "keyword" searches across the entire body of produced documents—more than 9,000,000 pages to date—to get at the handful of documents they intend to actually review and use, whereas AbbVie's attorneys need to read and understand the productions as a whole, not only to make privilege and confidentiality determinations, but also to understand the substance of those documents to better prepare the witnesses for

deposition and put into context any documents "cherry-picked" by Plaintiffs' counsel.[2] The differential burden on the parties will only be amplified as discovery continues; Plaintiffs can request files that they can review at no significant incremental cost, whereas each requested file adds significant burden to AbbVie without any indication that it will add meaningful probative value.

At the August 14th CMC the Court ordered that there would be a cap on the number of custodial files AbbVie would be required to produce and directed the parties to submit a proposal that would be entered without further argument. 8/14/15 CMC Tr. at 21, 50. Despite multiple offers made by AbbVie since June, Plaintiffs have never engaged meaningfully in any discussion of a cap on custodial file production. As a matter of principle they have never proposed a cap at all, opting to focus only on the production schedule. Even after the Court's directive at the last CMC, Plaintiffs remain unwilling to agree to ***any*** cap on custodial file productions. Simultaneously, Plaintiffs request the production of dozens of custodial files now (their Tier A list alone is 34 witnesses), and dozens to follow (25 witnesses on Tier B), with a promise that there are more requests to come. Plaintiffs ask this Court to impose on AbbVie the entire burden and risk of discovery without firm limits, with no associated requirement that Plaintiffs' requests be reasonable, focused, and proportional.

With no counter proposal from Plaintiffs, AbbVie requests that the Court enter an order adopting AbbVie's previously set forth proposal:

1. AbbVie will not be required to re-produce the 72 King/Solvay custodial files using MDL search terms. If Plaintiffs wish to request that a particular witness's file from the

[2] For example, to prepare for the recently completed deposition of Pablo Hernandez, AbbVie's attorneys conducted a page-by-page review of the entire custodial file of 67,000 documents, in addition to the millions of pages of "non-custodial" documents potentially relevant to the deposition. At the two-day deposition, Plaintiffs marked 32 exhibits, many of which did not come from Mr. Hernandez's custodial file.

King/Solvay production be produced using MDL terms they may do so, subject to the limits set forth below and the reasonable availability of those files.[3]

2. Production of custodial files will be capped at 65 (which is slightly more than 1.5x the number of deponents). This would include any files from the Solvay/King period, as referenced in item 1, the Pablo Hernandez file already produced, and the files of the witnesses requested for deposition in October and November (9 additional witnesses).

3. Following production and review of the 65 files, Plaintiffs may request up to 10 additional custodians' files focused on discrete, limited topics not already reasonably covered by others. AbbVie would not oppose the additional production on the basis of burden though AbbVie reserves the right to challenge good cause, as well as lack of relevance or some other substantive ground.

AbbVie anticipates that Plaintiffs will argue that a cap need not be set at this time because their current requests do not bump up against whatever they believe the cap will eventually be. This argument ignores the Court's instructions on this issue – specifically that a cap is needed to "incentivize people to make choices, intelligent choices about what they are going to get." 8/14/15 CMC Tr. at 21. Further, it was the Court's hope that the parties would be able to agree to what that cap should be. *Id.* at 50. The discussions over the last ten days with Plaintiffs have been virtually the same as they have been for months. Plaintiffs want more information, but will not commit to any limitations on their own requests.

Moreover, the open-ended approach touted by Plaintiffs is inconsistent with the Court's stated goals of establishing limits to guide the parties through discovery. AbbVie should not be placed in the position of having to review and produce still hundreds of thousands of more

[3] When the issue of the cap was first raised with the Court, Plaintiffs took their request for 72 additional Solvay witnesses off the table. 7/20/15 CMC Tr. at 42. With respect to the Solvay-era, Plaintiffs requested that AbbVie collect, review, and produce relevant documents from the *King v. Solvay* case, which AbbVie did (approximately 100,000 documents were produced). But Plaintiffs continue to be unsatisfied even after getting what they asked for. AbbVie remains willing to work with Plaintiffs to identify what information is available for individuals who were never Abbott/AbbVie employees, but this does not alter the equation for custodial file production. If AbbVie has a particular custodian's file, whether or not that person is a legacy Solvay employee, Plaintiffs can request production of that file and it will count against their cap.

documents without the framework for that production being in place. Given the production to date, the AbbVie witness deposition limit of 43, the aggressive schedule, and no cap proposal from Plaintiffs, AbbVie requests that the custodial file production limit be set as set forth above.

III. Custodial File Production Schedule

Plaintiffs' Position: On June 4, 2015, the PSC provided AbbVie's counsel with a list of 79 corporate witnesses whose files the PSC wanted produced. These witnesses were among the hundreds of people identified in AbbVie's Initial Disclosures and at the Rule 30(b)(6) corporate organization deposition of Ms. Leanne Walthers and in the Organizational Charts produced in connection with that deposition. The PSC distilled the information down to these 79 witnesses based on what was available to us at that time. At AbbVie's request, the PSC broke this group into three (3) groups/tiers for the timing of the production. In order to meet the schedule that the parties are striving to achieve in this MDL and to keep the MDL moving at a rapid but reasonable pace, the PSC has proposed the following timing for the production of these custodial files:

1. Expedited production of the remaining Tier A custodians so that the production of the remaining Tier A custodial files will be completed by October 15, 2015. Tier A is a total of thirty-four (34) custodians (one of whose file has been fully produced — Pablo Hernandez), many of whom are people identified by AbbVie in their initial disclosures as witnesses with relevant knowledge. Others in this Tier are witnesses whose files are already being processed for various reasons: nine (9) of which are for witnesses that the PSC has already requested in connection with the deposition of the witness and are expected to be produced by the end of September. Receiving these custodial files is imperative to keeping the MDL on track as the Tier A witnesses

were heavily involved with these products and the PSC expects that a significant number of Tier A custodians will be deposed.

2. The expedited production of Tier B custodians should follow the production of Tier A custodians such that the Tier B custodial files will be completed by November 15, 2015. There are twenty-four (24) Tier B witnesses identified in the MDL.
3. Mindful of the Court's guidance and intent to impose a presumptive cap on the number of custodians, Plaintiffs advised AbbVie that at the current time we do not think setting a deadline for the completion of the full set of Tier C custodians — as opposed to requesting a specific file should the need arise — is necessary. Setting a deadline can wait until after further review of documents and after some of the depositions are conducted. The PSC may determine some individuals' custodial files originally identified in Tier C are nonessential and at the same time, may also determine that different individuals' custodial files are necessary. Foregoing the production of Tier C custodians for the interim will also serve to keep the PSC sufficiently under AbbVie's proposed "cap" or presumptive limit on custodial files for the time being.

The PSC respectfully submits that being a year into the MDL and only having one completed custodial file (the Pablo Hernandez file, for which AbbVie has not yet provided a certificate of completion) puts the entire schedule at risk unless the pace of production quickens (both for custodial files and non-custodial storage areas) to put the MDL in a position where corporate depositions can be completed in time for expert discovery to proceed smoothly and efficiently.

AbbVie Position: At the August 14th CMC, the Court advised that the production of custodial files needed to "happen faster than the depositions" and that a production schedule needed to be set. 8/14/15 Tr. at 23. AbbVie's position will satisfy this goal. Within the next few weeks, Plaintiffs will have identified approximately 15 witnesses for deposition through the end of the year, approximately one-third of their deposition limit. Likewise, Plaintiffs have requested the production of files for the witnesses on their Tier A list – which will bring the total number of custodial files produced up to 31 – double the number of depositions requested. Producing those 31 files between now and the end of November fully complies with the Court's directive for production to outpace depositions, but in a way that is proportional and reasonable.

AbbVie assessed the volume of Plaintiffs' Tier A list to establish an aggressive yet realistic production deadline. By the end of this month, AbbVie will be producing the files for the witnesses Plaintiffs have requested for deposition in October. AbbVie has also agreed to produce the files of the witnesses for November depositions by the end of September (approximately 220,000 documents for review). To increase custodial file production over and beyond the witnesses set for deposition, AbbVie has agreed to produce, on a rolling basis, the remaining Tier A witnesses (an additional 21 custodial files) by the end of November 2015. Based on the search terms requested by Plaintiffs, those additional 21 files consist of another approximately 700,000 documents to be reviewed. This means that from now until the end of November, approximately 3 months, AbbVie has agreed to review another approximately 1 million documents for production. To meet the near term deadlines for depositions, AbbVie increased the size of the team reviewing documents, and will increase the team yet again to meet the November deadline (approximately a 40% staffing increase).

All of the productions will continue to occur on a rolling basis, so Plaintiffs will receive a continuous influx of documents. If even only 40% of the documents AbbVie reviews are responsive, Plaintiffs will receive 600,000 documents in a three month period. Further, these productions are over and above the ongoing non-custodial file productions which will continue to occur on a bi-weekly basis throughout this time. The November deadline proposed by AbbVie is extremely fast-paced. Any earlier deadline will likely result in errors brought by haste and inefficiencies (adding even more staffing, for example, will only hinder production as new people will need training and will be less knowledgeable than the core team). An earlier deadline thus will only lead to delay down the road and more importantly, will be virtually impossible to meet.

Plaintiffs have stated that regardless of the cap, they remain committed to the production for their Tier B list of witnesses as well, and have asked that a deadline for those files also be set. AbbVie has already begun collection of the files of those witnesses so that they will be processed and ready for review as soon as Tier A is complete. AbbVie will be in a better position to propose a deadline for that production after it is collected and the volume assessed. AbbVie proposes to provide a report to the Court on that volume in October.

For all of the foregoing reasons, AbbVie requests that the Court enter an order that the custodial files for Plaintiffs' Tier A witnesses be produced on a rolling basis to be completed by November 30, 2015.

Dated: August 24, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 24, 2015, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ Trent B. Miracle